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Australian Safety and Efficacy Register of New Interventional Procedures-Surgical

Systematic Review of Arthroscopic Subacromial Decompression Using The Holmium:YAG Laser

ASERNIP-S REPORT NO. 6

Australian Safety & Efficacy Register of New Interventional Procedures – Surgical

The Royal Australasian College of Surgeons

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Safety and Efficacy Classification for Arthroscopic Subacromial Decompression using the Holmium:YAG laser.

The ASERNIP-S Procedure Classifications were revised in December 1999 by the ASERNIP-S Management Committee. As such, procedures already assessed by ASERNIP-S were allocated a new classification from the following list;

1. Safety and efficacy is established. The procedure is equal to, or better than, the best practice based on the current available evidence. Procedure may be introduced into practice.

2. The safety and/or efficacy of the procedure cannot be determined at the present time due to an incomplete and/or poor quality evidence-base. The procedure should only be used with caution and it is also recommended that further research be conducted to establish safety and/or efficacy.

3. Safety and/or efficacy of procedure is shown to be unsatisfactory. Procedure should not be used.

The safety and efficacy classification for Arthroscopic Subacromial Decompression Using the Holmium:YAG Laser is 2.

References to previous classifications remain unchanged in the document.

Recommendations Regarding the Need for Further Research

In order to strengthen the evidence base regarding the procedure it is recommended that a controlled clinical trial, ideally with random allocation to an intervention and control group, be conducted.

The Royal Australasian College of Surgeons recognises that it may not always be possible to undertake a controlled clinical trial. Under such circumstances, it is recommended that at the very least, data be contributed to an audit for further assessment, in collaboration with ASERNIP-S, until such time as a controlled clinical trial is undertaken.

Important Note: The information contained in this report is a distillation of the best available evidence located at the time the searches were completed as stated in the protocol. Please consult with your medical practitioner if you have further questions relating to the information provided, as the clinical context may vary from patient to patient.

The Systematic Review of Arthroscopic Subacromial Decompression using the Holmium:YAG Laser, Recommendations and Safety and Efficacy Classification were ratified by the:

ASERNIP-S Management Committee
December 11th 1999

Council of the Royal Australasian College of Surgeons in February, 2000

Review Group Membership

ASERNIP-S Director
Professor Guy Maddern
ASERNIP-S
Royal Australasian College of Surgeons
NORTH ADELAIDE SA 5006

Protocol Surgeon
Mr Malcolm Wicks
Cransford House
399 South Terrace
ADELAIDE SA 5000

Advisory Surgeon
Mr Andrew Shimmin
42 The Avenue
WINDSOR VIC 3181

Other Specialty Surgeon
Mr David Watson
Department of Surgery
The Royal Adelaide Hospital
North Terrace
ADELAIDE SA 5000

Nominated Surgeon
(by Australian Orthopaedic Association)
Mr Graeme MacDougal
6 MacIntosh Street
CHATSWOOD NSW 2067

ASERNIP-S Researcher
Maggi Boult
ASERNIP-S
Royal Australasian College of Surgeons
NORTH ADELAIDE SA 5006

ASERNIP-S

Australian Safety and Efficacy Register of New Interventional Procedures-Surgical

Review Protocol

Arthroscopic Subacromial Decompression Using The Holmium:YAG Laser

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Dr Wendy Babidge and
Mrs Margaret Boult
ASERNIP-S Researchers
Royal Australasian College of Surgeons
North Adelaide
South Australia

Mr Malcolm Wicks
Orthopaedic Surgeon
The Upper Hand and Limb Clinic
333 South Terrace
Adelaide
South Australia

1. Objective

To assess the literature relating to the procedure **arthroscopic subacromial decompression using the Holmium:YAG laser**, and compare it to literature reviews of the "gold standard" **arthroscopic subacromial decompression (ASD)** for patients with impingement syndrome without full-thickness rotator cuff tears. Recommendations about the safety and efficacy of this new, minimally invasive shoulder surgery will then be made.

2. Background

Arthroscopic subacromial decompression is a surgical technique used to overcome shoulder impingement syndrome. Impingement syndrome results from narrowing of the space underlying the acromion and coracoacromial ligament. The syndrome is classified into three stages[1]:

- Stage I involves oedema/ haemorrhage
- Stage II shows fibrosis and irreversible tendon changes
- Stage III includes tendon rupture or tear.

Pain, weakness and loss of motion are the most common symptoms and the pain is exacerbated by overhead activities[1]. Impingement tests are used to assist in clinical assessment along with diagnostic testing such as plain radiographs[1,2]. Other imaging techniques such as arthrography, magnetic resonance imaging (MRI) or ultrasound are useful in diagnosing rotator cuff tears[2-4]. Treatment for impingement syndrome is with non-steroidal anti-inflammatory drugs (NSAIDs), rehabilitation, subacromial steroid injection or ASD[1,4,5].

Surgical management requires accurate diagnosis and documented failure of conservative therapy. Arthroscopic subacromial decompression was introduced in the mid-1980's and has proven to be a reliable alternative to open acromioplasty, especially for Stage II and Stage III (partial tear only) impingement syndrome[6]. This technique involves an acromioplasty, coracoacromial ligament resection, and bursectomy using a motorised shaver, burr and electrocautery[6,7]. As an alternative, use of the Holmium:YAG laser has been put forward as a tool to perform the same functions as the shaver, burr and electrocautery[6,8]. The reported benefit of the laser is in coagulation of small bleeding vessels in the process and reducing postoperative pain and swelling[6,8]. Laser ASD is a technically demanding procedure, which requires assessment of its safety and efficacy in comparison with the standard ASD.

Reference List

1. Fongemie AE, Buss DD, Rolnick SJ. Management of shoulder impingement syndrome and rotator cuff tears. *Am Fam Physician*. 1998;**57**:667-674.
2. Roye RP, Grana WA, Yates CK. Arthroscopic subacromial decompression: two- to seven-year follow-up. *Arthroscopy*. 1995;**11**:301-306.
3. Nutton RW, McBirnie JM, Phillips C. Treatment of chronic rotator-cuff impingement by arthroscopic subacromial decompression. *J Bone Joint Surg Br.* 1997;**79**:73-76.
4. Rodgers JA, Crosby LA. Rotator cuff disorders. *Am Fam Physician.* 1996;**54** (1):127-134.
5. Brox JI, Staff PH, Ljunggren AE, Brevik JI. Arthroscopic surgery compared with supervised exercises in patients with rotator cuff disease (stage ll impingement syndrome). *BMJ.* 1993;**307**:899-903
6. Imhoff A, Ledermann T. Arthroscopic subacromial decompression with and without the Holmium:YAG-laser. A prospective comparative study. *Arthroscopy*. 1995;**11**(5):549-556.
7. Green A. Arthroscopic treatment of impingement syndrome. *Orthop Clin North Am.* 1995;**26**:631-641.
8. Fanton GS, Dillingham MF. The use of holmium laser in arthroscopic surgery. *Sem Orthop.* 1992;**7** (2):102-116

3. Inclusion Criteria

Papers were selected for inclusion in this literature review on ASD using the Holmium:YAG laser on the basis of the following criteria.

- **Participants:**

Human studies were used for this review. Specifically, live human studies included adults:

- with impingement syndrome,
- without full-thickness rotator cuff tears,
- without rheumatological disorders, and
- with shoulder pain for > 3 months.

- **New Intervention:**

Papers relating to the new intervention, include the use of the Holmium Laser to perform acromioplasty, coacromial ligament resection and bursectomy.

- **Comparative or "gold standard" Intervention:**

Papers included for the comparative intervention were reviews of ASD for impingement syndrome without full-thickness rotator cuff tears, which represent the current safety and efficacy of this technique.

- **Outcomes:**

For a paper to be included it contained information on at least one of the following outcomes:

- Postoperative mortality
- Postoperative morbidity including blood loss
- Shoulder Score *
- Length of Hospital Stay
- Use of analgesics
- Time of return to normal activity
- Pain –at night, rest, movement
- Range of motion – active/passive
- Level of function/strength
- Length of surgery

It should be noted that there are a number of shoulder tests in use, differing considerably in emphasis on objective and subjective testing. As a consequence some of the other outcomes in this list are included within the shoulder score.

- **Types of studies:**

Papers included in the review of the new intervention were in one of the following forms:

- Randomised-controlled trials, controlled clinical trials (historical, non-randomised), case-series and case-reports.
- Additional published material in the form of letters, commentary and discussions was included in the submissions to the review surgeon as background information.
- Study types other than those mentioned above were included if they are felt to be relevant and if valid reasons are given in the protocol.

Papers included in the assessment of the comparative intervention are review articles published during the 1990's. Reviews provide a synthesis of the consensus opinion on the safety and efficacy of the procedure.

4. Exclusions

- The ASERNIP-S Data Manager and the Protocol Surgeon excluded references that clearly did not meet the inclusion criteria.
- Reasons are documented for excluding particular references that met the inclusion criteria.

5. Inclusions

One item recovered using the search criteria came from the American Academy of Orthopaedic Surgeons 1996 Annual Meeting Scientific Program, by Murphy *et al*. A subsequent author search was conducted to determine whether the information had been published in the peer-reviewed literature. The search was positive and the recovered item was included in the review. This helped to qualify the information that had been presented in the conference proceedings.

6. Additional Information

- Guidelines on assessing the published material in terms of methodological design and validity (i.e. hierarchy of study designs, bias, confounding, sample size, and statistical power) was sent to the Review Surgeon. Supplementary material on the review process was attached, including excerpts from The Cochrane Collaboration Handbook, and a copy of the NH&MRC 1999 guidelines: *A guide to the development, implementation and evaluation of clinical practice guidelines.*
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- As this review is an exclusively narrative systematic review, data is summarised in table format, rather than through meta-analysis.

7. Literature Search Strategies

- **Databases searched:**

- SilverPlatter Medline (WinSpirs)
- Ovid Current Contents
- The Cochrane Collection, The Cochrane Library CD 1998 Issue 4
- Lexis-Nexis Embase

- **Search Terms: -** Search strategies were devised by the Data Manager and Protocol Surgeon for the Medline, Current Contents and Embase databases.

1. New Intervention Search

   The search was performed to enable the retrieval of papers dealing with ASD using the Holmium:YAG laser for patients with impingement syndrome without full-thickness rotator cuff tears. The search terms entered were:

   > Laser and shoulder and (surgery or arthroscop* or acromioplasty or orthopaed* or orthoped* or subacromial decompression or impingement syndrome)

   The same search terms were utilised for all databases except for The Cochrane Collection database because the restricted searches turned up very few references.
   The simple search terms entered were:

   > 'Shoulder and Surgery'

2. Comparative Intervention Search

   This search was performed to enable retrieval of review articles published from 1990 on ASD without use of a laser. The search terms used were:

   > shoulder and (review in PT) and (surgery or arthroscop* or acromioplasty or orthopaed* or orthoped* or subacromial decompression or impingement syndrome) [since 1991; English]
   > where PT = publication type

- **Search Time Frame:**

1. SilverPlatter Medline (WinSpirs)

New Intervention	-	Year range = 1984 - October 1998
Comparative Intervention	-	Year range = 1991 - October 1998

2. Ovid Current Contents

New Intervention	-	Year range = 1993 - Week 45 1998
Comparative intervention	-	Year range = 1991 - Week 45 1998

3. Lexis-Nexis Embase

New Intervention	-	Year range = 1974 - October 1998
Comparative Intervention	-	Year range = 1990 - October 1998

4. The Cochrane Collection (The Cochrane Library CD 1998, Issue 4)

- Year range searched = 1966 - 1998

- **Literature Databases:**

New Intervention — **SADlaser.rmd:** 8 references formed the Reference Manager Database after exclusions of duplicates and articles that clearly did not meet the inclusion criteria[1].

Comparative Intervention — **reviewSAD.rmd:** 19 references formed the Reference Manager Database.

[1] See also inclusions

A Review on Arthroscopic Subacromial Decompression Using The Holmium:YAG Laser

Mrs Maggi Boult
ASERNIP-S

November, 1999

BACKGROUND SUMMARY

In 1983, Ellman pioneered the use of arthroscopic subacromial decompression (ASD) to treat chronic impingement syndrome in the shoulder[1].

Impingement syndrome results from a narrowing of the space underlying the acromion and coracoacromial ligament. In 1983, Neer described impingement as occurring *against the anterior edge and undersurface of the anterior third of the acromion, the coracoacromial ligament, and, at times, the acromioclavicular joint, rather than against the lateral acromion*[2]. Neer divided symptoms and physical signs of impingement lesions into three stages:

Stage I	Oedema and haemorrhage (reversible)
Stage II	Fibrosis and tendinitis
Stage III	Tears of the rotator cuff, biceps ruptures, and bone changes

Neer also described the use of the "impingement test". Pain can be elicited in patients with impingement lesions by a specific movement of the shoulder. This is referred to as the "impingement sign". An impingement test involves evaluating the pain before and after an injection of anaesthetic beneath the anterior acromion. If the pain is relieved by the anaesthetic then according to Neer the test is positive. This then helps to *separate impingement lesions of all stages from other causes of shoulder pain.*

Bigliani[3] however, states that impingement can be difficult to diagnose, particularly in younger patients and where other pathologies exist. Diagnosis requires careful assessment of patient history, physical examination, and radiography. Additional tests that may be done if a tear of the rotator cuff is suspected include ultrasound, MRI and arthroscopy.

It is recognised that Stage I and most Stage II lesions usually respond to conservative treatment[4]. However patients with Stage II lesions refractory to conservative treatment, and Stage III lesions are candidates for surgical intervention. Ellman's use of ASD followed on from other surgical modalities including the open anterior acromioplasty pioneered by Neer[5]. ASD involves acromioplasty, coracoacromial ligament resection and bursectomy using a motorised shaver, burr and electrocautery[6].

Whilst acknowledged as technically demanding[1], the advantages of ASD are thought to be lower surgical morbidity and quicker rehabilitation. The deltoid origin is preserved, enabling an early active rehabilitation program. In addition the use of arthroscopy enables direct visualisation of the glenohumeral joint, which may be helpful when diagnosis is not clear[4].

The procedure under review is a modified form of the ASD, which uses the Holmium:YAG laser in place of the shaver, burr and electrocautery[6,7]. Fanton and Dillingham[7] report first using the procedure in 1989, but there have been few published reports of its use. Advantages purport to be; less movement of instrumentation, haemostatic control, and reduction in soft tissue swelling. Fanton and Dillingham state that the Holmium:YAG laser is an *excellent hemostatic instrument that allows cutting, ablating, and contouring of tissues or bones while maintaining clear, blood-*

free visualization. The shortened operating time minimizes soft tissue swelling, and the decreased bleeding controls postoperative pain and inflammation.

In order to assess a new technique it needs to be compared to other procedures currently in use and specifically the recognised "gold standard", which for ASD using the Holmium:YAG laser is the open anterior acromioplasty operation. However, given the high level of acceptance for the ASD procedure it was felt that it was reasonable to use this as the comparator.

A number of review articles were selected using the search criteria described in the protocol. The articles selected provide information about the level of safety and efficacy for various procedures including ASD. The reviews include a Cochrane Centre Review on Interventions for Shoulder Pain[8]. This was completed in 1998 and provides a recent collation of evidence derived from randomised controlled trials of interventions for shoulder pain. For the purposes of this methodological review, the Cochrane Review provides an interesting overview of the level of available evidence.

ASSESSMENT OF ARTICLES FOR REVIEW

ASD with Holmium:YAG laser is being evaluated for safety and efficacy. A review group has been convened to compare this procedure with other established surgical methods used for the treatment of Impingement Syndrome.

There is a dearth of published literature on the new intervention. After searching the medical literature and applying the exclusion criteria listed in the Protocol, only eight articles were identified. These were disseminated to the ASERNIP-S Review Group.

The articles were assessed using NH&MRC Assessment Guidelines: Hierarchy of Evidence[17] (Table 1).

Table 1 Hierarchy of Evidence Source: NH&MRC

I	Evidence obtained from a systematic review of all relevant randomised controlled trials
II	Evidence obtained from at least one properly designed randomised controlled trial
III-1	Evidence obtained from well-designed pseudo-randomised controlled trials (alternate allocation or some other method)
III-2	Evidence obtained from comparative studies with concurrent controls and allocation not randomised (cohort studies), case-control studies or interrupted time-series with control group
III-3	Evidence obtained from comparative studies with historical control, two or more single arm studies or interrupted time series without a parallel control group
IV	Evidence obtained from case-series, either post-test or pre-test/post-test

METHODOLOGICAL REVIEW OF LITERATURE FOR ARTHROSCOPIC SUBACROMIAL DECOMPRESSION USING THE HOLMIUM:YAG LASER

None of the papers for review offered high quality evidence. There were no properly designed randomised controlled studies. Only three groups were identified as having published information relating to the new intervention[6,7,9-12].

The Imhoff group appears to have published three papers using the same patient group[6,9,10]. Two of these papers are written in German[9,10], and an assessment of these indicated that they supplied no additional evidence of safety and efficacy of the technique (*i.e.* improved statistical analysis, additional data). As a consequence it was not considered worthwhile having them translated. The one paper written in English was an interrupted time series with controls[6] [level III-2 evidence], comparing ASD +/- Holmium:YAG laser treatment. The control (ASD) group was operated on, one to two years prior to the laser group. Whilst the paper is described as prospective, it could be argued that it more appropriately fits in to level III-3 "Evidence obtained from comparative studies with historical controls". In addition the statistics in the paper are inadequately presented. For instance, the laser group was described as experiencing substantially less pain than the control group, but significance was reported as P=0.3. Graphs show mean results but not standard error.

The 1996 article by Murphy *et al*[12] was published as proceedings from a conference and was therefore not peer-reviewed prior to publication. This paper also describes a comparison of ASD +/- Holmium:YAG laser treatment and suggests that the authors conducted research which could be classified as level III-1 or level III-2 evidence. Due to the scant information available in the article it is hard to assess its methodological validity. The procedure for randomisation of patients to the two groups is not detailed. Pre and postoperative assessment does not appear to have involved any blinding. Statistical measures are inadequately described. Authors report no statistical differences between University of California, Los Angeles (UCLA) scores, blood loss, operative times, and patient satisfaction (at six months, one year, and final follow-up) for the two groups. The only statistical difference reported relates to costs, with the laser procedure being significantly more expensive.

The information reported by Murphy *et al*[12] for the conference proceedings appears to have been subsequently published in a peer reviewed journal[11]. The journal article offers more detailed information and can be classified as a pseudo-randomised controlled trial [level III-1 evidence]. The method of randomising patients is described as "drawing from a hat". There is no evidence to suggest however that the outcomes were assessed "blindly", thus introducing a source of bias into the study. The authors report the same outcomes as detailed above for the conference proceedings, and conclude that their data showed *no medical benefit to laser assisted arthroscopic subacromial decompression but that there was an increased monetary cost.*

Three articles could not be classified using the hierarchy of evidence table[7,13,14].

One is a description of the technique[7]. The authors, Fanton and Dillingham report having used the Holmium:YAG laser to perform ASD since 1989. The description of clinical experience is not open to methodological examination. No statistical analysis is given. Selection and exclusion criteria are not defined. Outcome measures are not described. For 200 patients, the authors report:

- Three patients required reoperation due to failure to adequately decompress the subacromial space (1.5%).
- Five patients required open capsular stabilisation (2.5%).
- Three patients required open repair (1.5%).
- One patient had superficial debridement of a painful portal site (0.5%).
- For two patients, the handpiece of the laser failed intra-operatively.

It should be noted that it is not clear how the 200 patients were selected, nor whether the same procedure was performed on each occasion.

One publication is a letter[13], published in response to Imhoff[6], and together with the response from Imhoff provides clarification on certain aspects of the procedure.

One paper describes the effect of laser ablation on cadaveric shoulder tissue[14]. The authors state that none of the lasers examined (including the Holmium:YAG) cut bone efficiently at the settings used. The pulsed Holmium:YAG laser removed synovial, bursal, labral, ligament and tendon tissue well.

A brief summary of all eight articles that describe the new intervention is given in Table 2. The design and outcomes of the Murphy and Imhoff studies are shown in Table 3.

SAFETY AND EFFICACY OF ARTHROSCOPIC SUBACROMIAL DECOMPRESSION

The Cochrane Review of Interventions for Shoulder Pain[8] identified 31 relevant trials and reviewed the efficacy of interventions. The review leveled serious criticisms about the methodological quality of the studies, with a lack of uniformity in outcome measures and in the way shoulder disorders are labeled and defined. They concluded that *there is little evidence to support or refute the efficacy of common interventions for shoulder pain*. The report made no specific mention of surgery for ASD.

In reviewing the literature for ASD, Bigliani[3] documents over 700 operations reported in 14 papers. Most outcomes were measured using the UCLA shoulder scoring system and satisfactory results (i.e. excellent to good) were recorded for 77-88% of patients. One study however recorded only 46% satisfactory results overall, falling to 32% for Workers Compensation patients. Complications reported included inadequate removal of bone and the development of acromial fracture.

Checroun *et al*[15] reviewed the literature from the last 25 years for open versus arthroscopic decompression for ASD. They reported an objective success rate of 83.3% versus 81.4% and a subjective success rate of 90.0% versus 89.3%.

Whilst the literature reviews undertaken by Bigliani and Checroun are extensive it should be remembered that the papers they were reviewing are the same ones assessed for the Cochrane Review and identified as having methodological weaknesses. Although most studies suggest that ASD has a similar outcome to open surgery these results should be treated cautiously.

A randomised, clinical trial performed by Brox *et al*[16] compared ASD with supervised exercises and a placebo laser treatment. After six months both arthroscopic surgery and exercises were better than placebo, but the difference between the active treatments were *neither clinically important or significant*.

Table 4 summarises the reported benefits versus risks and side effects for ASD. These were generally documented in reviews that were comparing the procedure to open acromioplasty.

SAFETY AND EFFICACY OF ARTHROSCOPIC SUBACROMIAL DECOMPRESSION USING THE HOLMIUM:YAG LASER

Given the low quality and quantity of evidence for ASD using the Holmium:YAG laser, very little can be concluded about its safety and efficacy from the literature.

Table 5 shows the **potential** risks and benefits for the ASD procedure with Holmium:YAG laser as described in the literature. In this case the authors are drawing comparisons with the non-laser arthroscopic procedure.

The paper by Murphy *et al*[11] provides the highest level of evidence available. No significant differences in outcomes were measured when comparing the ASD procedure with and without the use of the Holmium:YAG laser. The costs of the laser operation were reported as significantly higher. No benefits were shown.

Table 2 Summary of Literature

Brillhart 1996[13] Letter in response to Imhoff paper[6]. Brillhart questions amount of subacromial bone removed by laser, energy used and average settings. Also mentions that US FDA had not approved marketing of Holmium:YAG laser for use on bone. Imhoff response is given.
De Simoni 1996[9] German article with English summary. Level lll-2 evidence, prospective study of 47 patients. Suggest not worth translating. Paper appears to reiterate results shown by Imhoff, albeit with no statistical analysis. Possibly slightly longer follow-up of patients.
Fanton 1995[7] Broad description of the surgical shoulder techniques for which the Holmium:YAG laser can be used, including section on the subacromial space. Authors report clinical experience of "more than" 200 patients, but with no detail as to specific operation groups. They report complications but again without referring to specific operation.
Imhoff 1995[6] Level III-2 evidence- prospective study of 52 patients. Paper described more fully in Table 3. Note that conventional surgery was conducted prior to laser surgery. If historical controls were used the level of evidence would be III-3.
Imhoff 1994[10] Paper written in German language with English summary. Paper appears to use same data as that published by Imhoff 95[6].
Murphy 1996[12] Paper given to American Academy of Orthopaedic Surgeons 1996 Annual Meeting – scientific program. Not peer-reviewed. Reports results of randomised, prospective comparison of Holmium:YAG and electrocautery shoulder surgery for refractory impingement. Time series over 24 months. Assessed using UCLA and ASES shoulder scores. No significant differences found in shoulder scores or operation statistics between groups. Laser operation significantly more expensive.
Murphy 1999[11] Peer reviewed paper apparently using results described previously in conference proceedings[12]. Authors report results of randomised, prospective comparison of Holmium:YAG and electrocautery shoulder surgery for refractory impingement. No significant differences found in functional outcome, satisfaction, blood loss or operative time between groups. Laser operation significantly more expensive.
Vangeness 1995[14] Paper describes effect of Holmium:YAG, Neodymium:YAG and CO_2 lasers on cadaveric shoulders. Authors state that none of the lasers cut bone efficiently at parameters used. The pulsed Holmium:YAG laser removed synovial, bursal, labral, ligament and tendon tissue well. Fibreoptic delivery system and laser handpieces worked well.

Table 3 Review Table Summary

Level	Ref.	Intervention	Design	Sample Size	Study Period	Safety and Efficacy Outcomes	Other Statistics	Comments
III-1	Murphy *et al*., 1999	ASD +/-Ho:YAG laser. Laser set at 20 watts. A full-radius shaver and either a laser or cautery used to remove bursa and maintain haemostasis. Laser or cautery used to detach the acromial attachment of the coracoacromial ligament. Anterior acromioplasty performed with high speed burr. Associated procedures included acromioclavicular joint resection, cuff debridement, and glenohumeral joint debridement.	Prospective, pseudo-randomised controlled trial. Patients examined: pre-op, 1 week, 1, 2, 3, 6, 12 months. Evaluated using University of California Los Angeles (UCLA) & American Shoulder & Elbow surgeons (ASES) shoulder scoring systems. Inclusions & exclusions: Diagnosis of stage II impingement refactory to conservative treatment. Chronic symptoms > 4 months, no previous decompression surgery, good pain relief from subacromial injection of lidocaine, informed consent. All procedures completed by 1 or 2 surgeons using standardised technique.	49	enrolled Sep 93 - Dec 94.	UCLA scores at 1 month and subsequent visits showed no significant difference (NSD) in improvement between groups. NSD for blood loss, operative time or patient satisfaction (6 months, 1 year & final follow up) between groups. UCLA scores improved from poor to good at 1 year.	Actual figures not given. Authors report demographics not significantly different between groups, for sex, workers compensation, dominant arm involvement, or incidence of associated procedures. Laser group had lower average preop UCLA score (p=0.02) Sig diff in costs for two groups.	
III-2	Imhoff & Ledermann, 1995	ASD +/- Ho:YAG laser. Conventional surgery used shaver & electrocautery. New intervention with Ho:YAG (22watt) no electrocautery. No details of energy or settings used.	Interrupted time series: Non-randomised, prospective, non-concurrent controls Tested at preop, 10 days, 6 weeks, 6 months, 1 year. Evaluation using constant shoulder score, Imhoff-Balgrist score and questionnaire with items concerning changes in pain and mobility. Inclusions: impingement-syndrome type II or III, refractory to conservative treatment for > 6 months. Diagnosis of impingment based on history, painful arc and +ve impingement sign and test. Exclusion: full thickness tears of rotator cuff, severe labral pathology, concomitant distal clavicle resection, underlying glenohumeral instability. All procedures performed by or under direction of Imhoff.	34 - ASD+laser 18 - ASD-laser	conventional surg:Sep. 91 to Nov 92 Laser surgery: Feb 93 to April 94.	Inadequate presentation of descriptive statistics. Authors compare scores for pain, activities of daily living, range of motion, power and total score. Authors suggest outcomes favour laser group, but significance levels do not seem to show this, except perhaps for power. Average Constant score increased from 54.7 to 79.8 for laser group, and 50.3 to 68.7 for control.	Control av age = 46.5 Laser av. age = 46.5	Paper described as prospective, which puts level of evidence at III-2. If controls were historical it would become III-3.

Table 4 Reported Benefits and Risks for ASD

First Author	Reported Risks / Side Effects	Reported benefits
Altchek[4]	Failure of operation due to error in diagnosis. Inadequate bone resection, due to inadequate examination of "films" or inadequate bursectomy or continuous bleeding. Retention of coracoacromial ligament attachment may lead to recurrent impingement.	Less surgical morbidity and quicker rehabilitation. Better cosmesis. Preservation of the deltoid origin enabling active rehabilitation to start immediately postop. Direct visualisation can aid clinical diagnosis, and detect abnormalities. Earlier return to work.
Bigliani[3]	Incorrect or incomplete diagnosis of impingement, technical problem (not stated). Inadequate removal of bone necessitating revision operation. Development of acromial fracture postoperatively.	
Checroun[15]	Technically demanding with long learning curve. Failure due to inadequate acromial resection.	Checroun repeats Altcheks list: shorter periods of hospitalisation and rehabilitation; preservation of deltoid origin; earlier return to work and resumption of daily activities; better cosmesis; improved visualisation of intra-articular condition and evaluation of coexisting pathology. Decreased pain and narcotic intake, increased range of motion, decreased incidence of infection.

Table 5 Potential Benefits and Risks for ASD with Holmium:YAG laser

First Author	Risks / Side Effects	Benefits
Fanton[7]	Inadequate decompression of subacromial space. Persistant symptoms from shoulder instability and intrinsic rotator cuff pathology. Painful portal site. Handpiece failure.	"Fiberoptic laser technique allows for excellent control of bleeding, optimal fluid flow and visualisation, and precise dissection that significantly shortens surgical time and expedites recovery".
Imhoff[1]	Inadequate resection. Technically demanding.	"Cicatrized subacromial bursa can be cleanly stripped away and removed and the bleeding stopped. After the acromioplasty, the bony undersurface of the acromion is virtually sealed by the Holmium:YAG lasers". "Coracoacromial ligament can be detached and resected without further hemorrhage." "All bleeding vessels are closed off by photoablation". Improved abduction power. Reduced postoperative swelling.
Vangeness[14]	Unable to cut bone efficiently at parameters used. Increased heat and power "ablates bone by heat and photoacustic effects". Long learning curve, and training required.	Easy access to all areas of shoulder joint and subacromial space. All tissues around the shoulder except for bone were readily excised or debrided. Coagulation of bleeding tissues without complications.

Reference List

1. Ellman H, Kay SP. Arthroscopic subacromial decompression for chronic impingement. Two- to five-year results. *J Bone Joint Surg Br*. 1991;**73(**3):395-398.
2. Neer CS. Impingement Lesions. *Clin Orthop*. 1983;**173**:70-77.
3. Bigliani LU, Levine WN. Subacromial impingement syndrome. *J Bone Joint Surg Am*. 1997;**79**(12):1854-1868.
4. Altchek DW, Carson EW. Arthroscopic acromioplasty: Current status. *Orthop Clin North Am*. 1997;**28**(2):157-168.
5. Neer CS. Anterior acromioplasty for the chronic impingement syndrome in the shoulder. *J Bone Joint Surg*. 1972;**54** (1):41-50.
6. Imhoff A, Ledermann T. Arthroscopic subacromial decompression with and without the Holmium:YAG-laser. A prospective comparative study. *Arthroscopy*. 1995;**11**(5):549-556.
7. Fanton GS, Dillingham MF. 2.1um Holmium:YAG arthroscopic laser surgery of the shoulder. In Brillart A. ed. *Arthroscopic laser surgery*. New York: Springer-Verlag, 1995;239-225.
8. Green S, Buchbinder R, Glazier R, Forbes A. Soft Tissue: Systematic review of randomised controlled trials of interventions for shoulder pain. *Cochrane Library*. 1998;**3**:27.
9. De Simoni C, Ledermann T, Imhoff A. Holmium:YAG laser treatment of outlet impingement syndrome: medium-term results. *Orthopade* 1996;**25**:84-90. **German**.
10. Imhoff AB, Ledermann T. Schulter-impingement-syndrom: arthroskopische subakromiale dekompression mit Holmium:YAG-laser. *Arthroskopie*. 1994;**7**:158-169. **German**.
11. Murphy MA, Maze NM, Boyd JL, Qick DC, Buss DD. Cost-benefit comparison: Holmium laser versus electrocautery in arthroscopic acromioplasty. *J Shoulder Elbow Surg*. 1999;**8**(3):275-278.
12. Murphy MA, Maze N, Boyd J, Buss D. Arthroscopic subacromial decompression: randomized, prospective comparison of holmium laser versus electrocautery. *Orthopaedic Transaction*. 1996;**20**(1):18-19.
13. Brillhart AT. Arthroscopic subacromial decompression with and without the Holmium: YAG-laser [letter; comment]. *Arthroscopy*. 1996;**12**(2):263-264.
14. Vangeness CT, Smith CF. Arthroscopic shoulder surgery with three different laser systems: an evaluation of laser applications. *Arthroscopy: The Journal of Arthroscopic and related surgery*. 1995;**11**(6):696-700.
15. Checroun AJ, Dennis MG, Zuckerman JD. Open versus arthroscopic decompression for subacromial impingement. A comprehensive review of the literature from the last 25 years. *Bulletin Hospital for Joint Diseases*. 1998;**57**(3):145-151.
16. Brox JI, Staff PH, Ljunggren AE, Brevik JI. Arthroscopic surgery compared with supervised exercises in patients with rotator cuff disease (stage II impingement syndrome). *BMJ*. 1993;**307**(6909):899-903.
17. National Health and Medical Research Council. A designation of levels evidence. *Guide to the development, implementation and evaluation of clinical practice guidelines.* Commonwealth of Australia. 1999; Appendix B, 52. http://www.nhmrc.health.gov.au/publicat/pdf/cp30.pdf

Safety and Efficacy Classification

The ASERNIP-S Procedure Classifications are selected from the following list:

1. Safety and efficacy is established. Procedure is equal to, or better than the nominated gold standard. Procedure may be introduced into practice.

2. The safety and efficacy of the procedure cannot be determined due to an incomplete and/or poor quality evidence-base. One of the following recommendations is made:

   2.1 An audit is required.

   2.2 A Controlled Clinical Trial, preferably prospective with concurrent controls, is required.

   2.3 A Randomised Controlled Clinical Trial is required.

3. Safety and efficacy of procedure is shown to be unsatisfactory. Procedure should not be used.

The classification for Arthroscopic Subacromial Decompression using Holmium:YAG laser is 2.3. *A Randomised Controlled Clinical Trial is required to assess both safety and efficacy.*

Review Group Comments

The Review Group members agreed that the safety and efficacy of the procedure could not be determined due to insufficient and poor quality supporting evidence.

The decision in favour of a 2.3 classification was reached by consensus.