

## ROBOT-ASSISTED RADICAL PROSTATECTOMY *A Technology Assessment*

### INTRODUCTION

The California Technology Assessment Forum is requested to review the scientific evidence for the use of robot-assisted laparoscopic radical prostatectomy (RALP) for treatment of clinically localized prostate cancer.

### BACKGROUND

Prostate cancer is the most common cancer in men in the United States, accounting for approximately 29% of all incident cancers (excluding non-melanoma skin cancers) in 2007. It is the second most common cause of cancer death; the American Cancer Society estimates that prostate cancer was responsible for the death of 27,050 U.S. men in 2007. While prostate cancer is common in North America and Europe, it is less common in Asia and South America; both incidence and death from prostate cancer are highest among African American and Jamaican men of African descent. The vast majority of prostate cancers (90%) are diagnosed in early clinical stages; five-year survival for these tumors approaches 100%.<sup>1</sup>

#### *Prostate Cancer Mortality*

While survival of prostate cancer has certainly improved over the last 15 years, it is unclear how much of that is due to earlier receipt of necessary treatment versus lead-time bias (diagnosing disease earlier, but not actually prolonging life)<sup>2</sup>. The advent of prostate specific antigen (PSA) screening has contributed to a rise in disease incidence<sup>1</sup>, in part because it has allowed for detection of early stage disease confined to the prostate gland. It is widely debated, however, whether all early stage disease requires active treatment, or whether active surveillance (or watchful waiting) is sufficient<sup>3-6</sup>. There is no randomized control trial (RCT) of the gold standard surgical treatment, open retropubic radical prostatectomy (ORP) compared to active surveillance primarily in men with PSA-detected disease<sup>6</sup>. However, at least in one RCT, ORP does appear superior to active surveillance for men with palpable tumors clinically confined to the prostate (stage T2), reducing ten-year disease-specific deaths from 15% to 10% and ten-year incidence of distant metastases from 23% to 14%<sup>7</sup>.

#### *Positive Surgical Margins*

Microscopic tumor found at the edge of a pathologic specimen after prostatectomy is considered a positive surgical margin. Positive margins are known to confer some risk for biochemical (PSA) recurrence<sup>8-10</sup>.

However, it is also clear that other clinical factors, such as Gleason grade, cancer volume, intra-prostatic vascular invasion, baseline PSA are also significant determinants of disease recurrence or progression<sup>11</sup>. Thus, it is important that any non-randomized trial using margin status as a surrogate marker for disease progression at a minimum adjust for these clinical predictors.

#### *Robot Assisted Laparoscopic Radical Prostatectomy*

RALP is performed by a surgeon using a three-armed robot. Rather than an open procedure with a single abdominal incision, there are five small holes in the abdominal wall, allowing for introduction of the robot and attached instruments. The procedure is currently being performed in clinical centers in the United States and Europe. The potential benefits of RALP include the three-dimensional nature of the images provided by the robot, magnification allowing for nerve-sparing procedures and possible improved continence and sexual function outcomes, less blood loss, less postoperative pain, and shorter hospital stays.<sup>12</sup>

### **TECHNOLOGY ASSESSMENT (TA)**

**TA Criterion 1: The technology must have final approval from the appropriate government regulatory bodies.**

The Intuitive Surgical® Endoscopic Instrument Control System (referred to as the “da Vinci™ System”) (Intuitive Surgical, Inc., Sunnyvale, CA) was cleared through the FDA 510(k) process on May 30, 2001

The ZEUS® Robotic Surgical System (Computer Motion, Inc., Goleta, CA) was cleared through the FDA 510(k) process on October 5, 2001.

TA Criterion 1 is met.

**TA Criterion 2: The scientific evidence must permit conclusions concerning the effectiveness of the technology regarding health outcomes.**

The Medline database, Cochrane clinical trials database, Cochrane reviews database and the Database of Abstracts of Reviews of Effects (DARE) were searched using the key words ‘prostate’, cross-referenced with the keyword ‘robotic surgery’. The search was performed for the period from 1966 to May 2008, and was limited to the English language. The bibliographies of key articles were manually searched for additional references. The abstracts of citations were reviewed for relevance and all potentially relevant articles were reviewed in full. Studies were included if they reported data on a minimum of 20 cases. We found 27 relevant published studies, 13 of which were case series of men undergoing RALP<sup>13-24</sup>, and 14 of

which were comparative trials of RALP versus either ORP or laparoscopic radical prostatectomy (LRP) or both<sup>25-38</sup>. Overall, the publications covered the three most important types of health outcomes in evaluating effectiveness of prostatectomy<sup>39</sup>: oncologic (margin status and biochemical/PSA recurrence), functional (urinary continence, sexual function, health-related quality of life), and peri-operative (operative time, hospital length of stay, blood loss, post-operative pain, complications). Several publications spanned either all three or two of three outcome types, and there were comparative trials in each of these areas. We did not find any RCTs of RALP.

Level of Evidence: 3, 4, 5  
TA Criterion 2 is met.

### TA Criterion 3: The technology must improve net health outcomes.

#### *Oncologic Outcomes*

We found 18 publications which examined oncologic outcomes. Eleven of these were case series which ranged in size from 140 to 2,766 participants<sup>13, 14, 16-24</sup>. Four examined the impact of a procedural learning curve on rates of positive margins. While three studies found a marked improvement over time from 45% positive margins with the first third of 140 cases to 12% with the last third of cases in one study<sup>13</sup>, an improvement from 36% to 17% in another study,<sup>20</sup> and an improvement from 23% to 11% in the third study<sup>17</sup>, a fourth study found no difference between the first 15 cases (26%) and at least 81 cases (22%) in overall rate of positive margins, but a significant drop in rate of 'extensive' positive margins from 12% to 2%<sup>19</sup>. When not examining learning curve, the case series report a positive margin rate of 9% to 21%. Seven of the case series also examined PSA recurrence, and found low rates of PSA recurrence (4-8%) at short-term follow-up ranging from six to 22 months, but primarily less than a year<sup>16-18, 22-24</sup>. These studies were conducted at single sites, sometimes with single surgeons, and none of them adjusted for other important clinical prognostic indicators such as baseline PSA, Gleason score, clinical T-stage or prostatic volume. None reported on mortality or long-term outcomes.

Of the eight comparative studies examining oncologic outcomes, five compared RALP to ORP<sup>28, 30, 33, 35, 38</sup>, two compared to both ORP and LRP<sup>29, 37</sup>, and one compared to LRP only<sup>27</sup>. One small study of only 38 cases found a statistically non-significant higher rate of positive margins (28% vs. 8%;  $p=.22$ ) and higher rate of PSA recurrence for RALP compared to ORP (10% vs. 0%;  $p=.52$ )<sup>28</sup>. Another larger study found a significantly lower rate of positive margins for RALP compared to

ORP, but had unusually high rates of positive margins for ORP (15% vs. 36%  $p < .01$ )<sup>33</sup>. The remaining studies found no difference between RALP and ORP or LRP<sup>27, 29, 30, 35, 37, 38</sup>. All of these studies suffer from significant methodologic problems. None of them were randomized and thus there could be bias in case-selection for a given surgical approach. All of them were at single institutions, sometimes with single surgeons, making it difficult to generalize the results. None of them report blinding for outcome adjudication, thus the individuals determining margin status or PSA recurrence were not blinded to the type of surgical approach, which could introduce bias into the results. Frequently, the two groups being compared were not concurrent, thus differences in outcomes could be associated with temporal differences in care rather than to operative approach. In many of these studies, the majority of the cases were stage T1c; these are just the cases that might do well with active surveillance, or at least for whom ORP has not been definitively proven beneficial<sup>40</sup>. Lastly, margin status is a surrogate marker for disease recurrence, and none of these studies adjusted for other potential predictors of disease recurrence.

Table 1. Publications of Comparative Studies Examining Robot-assisted Radical Prostatectomy and Oncologic Outcomes.

Study (N)	Study Type	Outcome Measure	Results	Critique
<b>Menon 2002<sup>30</sup> (60)</b>	Prospective comparison (non-randomized) RALP vs. ORP	Margin Status	RALP and ORP no difference in incidence of positive margins (26% vs. 29%; p NS)	Single site; No randomization; No blinding for outcome adjudication; All RALP performed by single surgeon; ORP performed by 8 different surgeons; No adjustment for potential confounding; Majority of all cases were clinical stage T1c pre-operatively.
<b>Ahlering 2004<sup>35</sup> (120)</b>	Retrospective comparison (non-randomized) RALP vs. ORP	Margin Status	RALP and ORP no difference in incidence of positive margins (17% vs. 20%)	Single site; Single surgeon No randomization; No blinding for outcome adjudication; No adjustment for potential confounding.
<b>Joseph 2005<sup>27</sup> (100)</b>	Retrospective comparison (non-randomized) RALP vs. LRP	Margin Status  PSA	RALP and LRP no difference in incidence of positive margins (12% vs. 14%)  At mean 5.3 months follow-up no PSA recurrence	Single site; No randomization; No blinding for outcome adjudication; No adjustment for potential confounding; Majority of all cases were clinical stage T1c pre-operatively.
<b>Menon 2005<sup>29</sup> (600)</b>	Prospective comparison (non-randomized) RALP vs. ORP vs. LRP	Margin Status  PSA	No difference in odds of a positive margin among three groups. (23% in ORP group; unclear what percent in other two groups).  Non-significant lower odds of detectable PSA for RALP vs. ORP; no difference for LRP.	Single site; No randomization; No blinding for outcome adjudication; Authors don't provide actual raw numbers; used logistic regression, but unclear to what the odds ratios refer; Unclear if authors adjusted for clinical factors in analysis or simply presented unadjusted odds ratios.

Study (N)	Study Type	Outcome Measure	Results	Critique
<b>Kohl 2007<sup>28</sup> (38)</b>	Retrospective comparison (non-randomized) RALP vs. ORP	Margin Status  PSA	RALP vs. ORP higher rate of positive margins, but non-significant difference (28% vs. 8%; p=.22)  At mean 12.5 month follow-up fro RALP and mean 24.5 month follow-up for ORP, majority in both groups with no PSA recurrence (90% vs. 100%; p=.52)	Single site Single surgeon No randomization; No blinding for outcome adjudication; No adjustment for potential confounding; Unequal numbers per group; both small groups. Differential rates of follow-up for two groups.
<b>Rozet 2007<sup>37</sup> (266)</b>	Prospective comparison (non-randomized) RALP vs. LRP; Analysis: matched-paired on age, BMI, previous abd surgery, pre-op PSA, clinical stage, Gleason score	Margin Status	No difference in margin status for RALP vs. LRP (19.5% vs. 15.8%; p=.42)	Singe site; No randomization; No blinding for outcome adjudication.  Strengths: matched-pair analysis; concurrent comparison groups.
<b>Smith 2007<sup>33</sup> (400)</b>	Retrospective comparison (non-randomized) RALP vs. ORP	Margin Status	Lower incidence with RALP vs. ORP: (15% vs. 36%; p<.001)  Apex most common site of positive margins in both groups	Single site; Not all surgeons performed both types of surgeries; No randomization; No blinding for outcome adjudication; Significant clinical differences between groups (PSA, Gleason score, pathological stage), but no adjustment for these in analysis
<b>Wood 2007<sup>38</sup> (206)</b>	Prospective comparison (non-randomized); RALP vs. ORP	Margin status	No significant difference in rate of positive margins (RALP 18% vs. LRP 9%; p=.1)	Single site No randomization; No blinding for outcome adjudication; No adjustment for potential confounding.

*Functional Outcomes*

We found 11 publications which examined RALP and functional outcomes. Of these, six were case series<sup>15, 17, 18, 22-24, 40</sup>, and five were non-randomized comparative studies<sup>25, 27, 29, 31, 35</sup>. Of the six case series, two reported both high rates of urinary continence and of sexual function at six to twelve months<sup>18, 24</sup>, another reported moderate rates of sexual function particularly improved for those patients with bilateral nerve-sparing procedures<sup>15</sup>, and three reported 95% of cases with full continence at six to twelve months<sup>17, 22, 23</sup>.

Among the comparative studies (Table 2) - with the exception of one study which showed no difference between RALP and LRP in very high rates of total urinary continence at three months (90% vs. 92%)<sup>27</sup>, and another which showed no difference between RALP and ORP in rates of full continence at three months (76% vs. 75%)<sup>35</sup> - the remainder demonstrated shorter times to somewhat higher rates of urinary continence and sexual function for RALP vs. ORP, and in two studies vs. LRP as well. One study reported higher quality of life in post-op weeks 3-6 for RALP vs. ORP based on the physical component scale on the SF-12; however at the end of six weeks it appeared that the two curves might be coming closer together<sup>31</sup>. Again, these are single site, non-randomized studies which - with the exception of the quality of life study - do not adjust for potential confounding in their analyses. Thus, these results are suggestive of possible improved functional outcomes with RALP, but not conclusive.

Table 2. Publications of Comparative Studies Examining Robot-assisted Radical Prostatectomy and Functional Outcomes.

Study (N)	Study Type	Outcome Measure	Results	Critique
<b>Ahlering 2004<sup>35</sup> (120)</b>	Retrospective comparison (non-randomized) RALP vs. ORP	Urinary continence	No difference between RALP and ORP in rate of complete continence at 3 months (76% vs. 75%)	Single site; Single surgeon No randomization; No blinding for outcome adjudication; No adjustment for potential confounding.
<b>Menon 2005<sup>29</sup> (600)</b>	Prospective comparison (non-randomized) RALP vs. ORP vs. LRP	Median time to continence  Median time to erection  Median time to intercourse	RALP with shorter median time to continence than ORP or LRP. RALP with shorter median time to erection than ORP; not measured for LRP cases. RALP with shorter median time to intercourse than ORP; not measured for LRP cases.	Single site; No randomization; No blinding for outcome adjudication; Authors don't provide actual raw numbers; used logistic regression, but unclear to what the odds ratios refer; e.g. lower odds of what cutoff time to continence, erection or intercourse. Unclear if authors adjusted for clinical factors in analysis or simply presented unadjusted odds ratios.
<b>Miller 2007<sup>31</sup> (162)</b>	Prospective comparison (non-randomized) RALP vs. ORP	Quality of Life measured by SF12 – physical component score (PCS) and mental component score (MCS) (adjusted for age, blood loss, baseline values)	Higher PCS for RALP vs. ORP from week 3-6 post-operatively; Higher MCS for RALP vs. ORP at baseline and 1 week post-operatively; no difference from 2-6 weeks.	Single site; No randomization; Unequal n in two groups; Unclear if difference in PCS would remain beyond 6 weeks as curves appear to be coming closer together at 6 weeks.
<b>Ball 2006<sup>25</sup> (341)</b>	Prospective comparison (non-randomized) ; RALP vs. ORP vs. LRP	Sexual function at 3 months  Urinary continence	At 3 months, sexual function higher in RALP vs. ORP and LRP (35% vs. 24% vs. 21%; p=.03) At 1 month, urinary function was higher for RALP and ORP than for LRP (39% vs. 37% vs. 24%; p=.03)	Single site; No randomization; No adjustment for potential confounding.
<b>Joseph 2005<sup>27</sup> (100)</b>	Retrospective comparison (non-randomized) RALP vs. LRP	Urinary continence at 3 months post-operatively	RALP vs. LRP no difference in rate of total urinary continence at 3 months (90% vs. 92%; p NS)	Single site; No randomization; No blinding for outcome adjudication; No adjustment for potential confounding;

*Peri-operative Outcomes*

We found 18 publications evaluating RALP and peri-operative outcomes, seven of which were case series<sup>14, 17, 18, 21-24</sup>, 11 of which were non-randomized comparison studies<sup>26, 27, 29-32, 34-38</sup>. The case series report peri-operative outcomes for RALP, including operative time ranging from 130 to 282 minutes, estimated blood loss from 75mL to 274mL, and average length of hospital stay from 1 to 1.8 days. The comparison studies examining peri-operative outcomes are detailed in Table 3. Those examining operative time and blood loss found that RALP had shorter operative times and less blood loss than ORP. However, blood loss was relatively low for both surgical approaches, with few patients requiring transfusions in any study. The comparison studies examining post-operative pain found low pain scores for both surgical approaches, and where there were differences they appeared to be short-lived and not to impact significantly on use of narcotic analgesia<sup>29, 30, 34, 38</sup>. While Menon et al report fewer complications related to RALP than to ORP, they do not specify the number or type of complications<sup>29</sup>; the one other study which specifically reported on complications found no difference between RALP and ORP in frequency of complications related to urinary drainage<sup>32</sup>.

Table 3. Publications of Comparative Studies Examining Robot-assisted Radical Prostatectomy and Peri-operative Outcomes.

Study (N)	Study Type	Outcome Measure	Results	Critique
<b>Menon 2002<sup>30</sup> (60)</b>	Prospective comparison (non-randomized) RALP vs. ORP	Operative time Blood loss Post-operative Hb Post-op pain Days of catheterization	RALP longer operative time than ORP (4.8hr vs. 2.3hr; p<.001) RALP less blood loss than ORP (329mL vs. 970 mL; p<.001) RALP with less drop in Hb than ORP (1.2g/dL vs. 4.4 g/dL; p<.05) RALP lower post-op pain score (POD#1) 4 vs. 7 (p<.05) No difference in days of catheterization.	Single site; All RALP performed by single surgeon; ORP performed by 8 different surgeons; No adjustment for potential confounding; Operative time did not include the 'setup' time required for RALP.
<b>Ahlering 2004<sup>35</sup> (120)</b>	Retrospective comparison (non-randomized) RALP vs. ORP	Blood loss Post-operative Hb / transfusion rate Hospital stay	RALP less blood loss than ORP (103mL vs. 418 mL; p<.001) RALP less change in Hb than ORP (-1.6g/dL vs. -3.3g/dL; p<.001); RALP group zero transfusions; ORP group 1 transfusion. RALP shorter LOS than ORP (26hr vs. 53hr; p<.001),	Single site; Single surgeon No randomization; No blinding for outcome adjudication; No adjustment for potential confounding.
<b>Menon 2005<sup>29</sup> (600)</b>	Prospective comparison (non-randomized) RALP vs. ORP vs. LRP	Operative time Blood loss Postoperative pain Complications	RALP had shorter operative time; LRP had longer operative time than ORP. Both RALP and LRP had less blood loss than ORP. Both RALP and LRP had lower pain scores than ORP; Both RALP and LRP had fewer complications than ORP	Single site; No randomization; No blinding for outcome adjudication; Authors don't provide actual raw numbers; used logistic regression, but unclear to what the odds ratios refer; e.g. lower odds of what operative time, how much blood loss, which complications. Unclear if authors adjusted for clinical factors in analysis or simply presented unadjusted odds ratios.
<b>Joseph 2005<sup>27</sup> (100)</b>	Retrospective comparison (non-randomized) RALP vs. LRP	Operative time Blood loss	RALP vs. LRP no difference in mean operating time (277 vs. 264 min; p=NS) RALP vs. LRP less blood loss (206 vs. 299mL; p.01). No transfusions in either group.	Single site; No randomization; No blinding for outcome adjudication; No adjustment for potential confounding;

<b>Farnham 2006<sup>26</sup> (279)</b>	Prospective comparison (non-randomized) RALP vs. ORP	Blood loss Peri-op change in HCT Discharge HCT Blood transfusion	Mean blood loss less for RALP vs. ORP (191mL vs. 664 mL; p<.001) Mean drop in HCT (8% vs. 10.7%; p<.001) Mean discharge HCT (36.8% vs. 32.8%; p<.001) No difference in transfusion requirement RALP vs. ORP (.5% vs. 2.9%; p=.14)	Single site; Single surgeon; No randomization; No blinding for outcome adjudication; No adjustment for potential confounding; Although some findings statistically significant, unclear actual clinical significance as only 4 patients required blood transfusions.
<b>Hu 2006<sup>36</sup> (680)</b>	Retrospective comparison (non-randomized) RALP vs. LRP	Operative time Blood loss Blood transfusion Urinary leakage post-op Ileus in immediate post-op period	Operative time RALP 3.1h vs. LRP 4.1hr; Similar blood loss RALP 250mL vs. LRP 200mL; Similar low rates of transfusion RALP 1.6% vs. LRP 2.2%. Urinary leakage RALP 7.5% vs. LRP 13.5%; Ileus RALP 2.8% vs. LRP 5.3%.	Single site; No randomization; No blinding for outcome adjudication; Non-concurrent comparison groups; No statistical tests given; no adjustment for potential confounding.
<b>Webster 2005<sup>34</sup> (314)</b>	Prospective comparison (non-randomized) RALP vs. ORP	Post-operative narcotic use Self-reported pain	Mean narcotic use adjusted for length of stay no difference between RALP and ORP (p=.72); Mean pain scores low overall in both groups; lower on operative day for RALP vs. ORP (2.05 +/-1.99 vs. 2.60 +/-2.5; p=.03), but no difference on post-op Day #1 or #14 (p=.88 and .72)	Single site; No randomization; No blinding for outcome adjudication; No adjustment for potential confounding.
<b>Miller 2007<sup>31</sup> (162)</b>	Comparison (non-randomized) RALP vs. ORP	Blood loss	Mean blood loss RALP greater than ORP (232mL vs. 490mL; p<.0001)	Single site; No randomization; Unequal n in two groups; No adjustment for potential confounding.
<b>Sharma 2007<sup>32</sup> (325)</b>	Prospective comparison (non-	Complications related to pelvic drainage	No difference in frequency of complications in RALP vs. ORP groups (p>.05).	Single site; No randomization; No adjustment for potential confounding;

	randomized); RALP vs. ORP			No blinding for outcome adjudication.
<b>Rozet 2007<sup>37</sup> (266)</b>	Prospective comparison (non-randomized) RALP vs. RLP; Analysis: matched-paired on age, BMI, previous abd surgery, pre-op PSA, clinical stage, Gleason score	Operative time Blood loss Hospital Stay	No significant difference between RALP and LRP in operative time (166min vs. 160min; p=.09); blood loss (RALP 609mL vs. LRP 512mL; p=.07); or LOS (RALP 5.4 days vs. LRP 4.9 days; p=.21)	Single site; No randomization; No blinding for outcome adjudication.  Strengths: matched-pair analysis; concurrent comparison groups.
<b>Wood 2007<sup>38</sup> (206)</b>	Prospective comparison (non-randomized); RALP vs. ORP	Operative time Blood loss Hospital Stay Pain Control  Time to activity	Mean operative time RALP vs. ORP (210 vs. 163min; p<.001); Mean blood loss RALP vs. ORP (150 vs. 707mL; p<.001); No difference in length of stay RALP vs. ORP (1.2 vs. 1.3 days; p=.05); Slightly more narcotic use in hospital for ORP (RALP 32mg vs. ORP 52mg; p=.001), but no difference in post-discharge days of narcotic use with low and equivalent pain scores in both groups at 2 and 6 weeks post-op; No significant difference in time to normal activity, time to 100% activity, or time to driving.	Single site No randomization; No blinding for outcome adjudication; No adjustment for potential confounding;

TA Criterion 3 is not met.

**TA Criterion 4: The technology must be as beneficial as any established alternatives.**

While there remains doubt as to whether there is a clearly superior effective treatment for early-stage prostate cancer - particularly for patients' whose cancer was diagnosed based on an elevated PSA<sup>6</sup> - the standard surgical approach to prostatectomy is widely considered to be ORP. The vast majority of the cited literature above which compared RALP to another treatment approach compared it to ORP. These non-randomized comparative studies are suggestive that RALP is at least equal to ORP in peri-operative and functional outcomes. The studies of oncologic outcomes are again suggestive, but focus largely on a surrogate marker (margin status) without true disease recurrence or mortality data. In addition, none of the studies are definitive due to their non-randomized nature and the lack of analytic rigor and adjustment for potential confounders.

**TA Criterion 4 is not met.**

**TA Criterion 5: The improvement must be attainable outside of the investigational setting.**

Because RALP has not yet been established in clinical trials as improving net health outcomes for men with early stage prostate cancer, we cannot evaluate whether any improvement is attainable outside investigational settings. However, if in the future net health outcomes are proven with RALP, because most of the studies of RALP have been conducted in large clinical centers it appears that its use need not be confined to investigational institutions. It is important to note that there is clearly a learning curve requiring training of individual surgeons. Further work should be done to improve training through simulation activities and supervision in order to avoid poorer outcomes for patients who are treated in the early part of a surgeon's learning curve. Some experts have recommended that hospital policies require specific accreditation and standards – separate for that for traditional laparoscopic surgery - for surgeons who wish to use this new robot-assisted technology in their practice<sup>41</sup>.

**TA Criterion 5 is not met.**

## **CONCLUSION**

While RALP is a promising technological advance for less invasive surgical treatment of early-stage prostate cancer, the studies to date are only suggestive of potential net health benefit as compared to the open

approach. It remains necessary both to establish equivalence with ORP in oncologic outcomes and to confirm and further quantify the benefit in both functional and peri-operative outcomes. This requires a multi-center randomized control trial, randomizing equivalent patients to RALP and ORP. Unless an appropriate RCT is done, the currently published results suggesting improved outcomes with RALP remain in doubt in particular due to concerns about case selection bias and possible significant differences between the groups who underwent RALP versus ORP.

### **DRAFT RECOMMENDATION**

It is recommended that robot assisted laparoscopic radical prostatectomy as a treatment of clinically localized prostate cancer does not meet CTAF criteria 3-5 safety, effectiveness and improvement in health outcomes.

June 18, 2008

## RECOMMENDATIONS OF OTHERS

### BLUE CROSS BLUE SHIELD ASSOCIATION (BCBSA)

The BCBSA Technology Evaluation Center has not conducted a review of this technology.

### CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

The CMS web site is silent on the use of robotic-assisted prostatectomy. At this time, CMS would consider this as "prostatectomy by any method".

### CALIFORNIA UROLOGICAL ASSOCIATION (CUA)

The CUA has been invited to participate at the meeting and has provided an opinion statement.

## ABBREVIATIONS USED IN THIS REVIEW

RALP	Robot-assisted laparoscopic radical prostatectomy
PSA	Prostate specific antigen
RCT	Randomized control trial
ORP	Open retropubic radical prostatectomy
DARE	Database of Abstracts of Reviews of Effects
LRP	Laparoscopic radical prostatectomy
PCS	Physical component score
MCS	Mental component score
ED	Erectile dysfunction
HCT	Hematocrit
Hb	Hemoglobin
BCBSA	Blue Cross Blue Shield Association
CMS	Centers for Medicare and Medicaid Services
CUA	California Urological Association

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